

§ 520.763b

of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763b Dithiazanine iodide powder.

(a) *Chemical name.* 3-Ethyl-2-[5-(3-ethyl-2-benzothiazolinyliidene)-1,3-pentadienyl]-benzothiazoliumiodide.

(b) *Specifications.* Dithiazanine iodide powder contains 200 milligrams of dithiazanine iodide per level standard tablespoon.

(c) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) Dithiazanine iodide powder is administered to dogs by mixing the proper dosage in the dog's food, using the following dosage schedule for various parasite infestations:

	Milligrams per pound of body weight	Length of treatment—days
Large roundworms (<i>Toxocara canis</i> , <i>Toxascaris leonina</i>)	10	3-5
Hookworms (<i>Ancylostoma caninum</i> , <i>Uncinaria stenocephala</i>)	10	7
Whipworms (<i>Trichuris vulpis</i>)	10	7
Strongyloides (<i>Strongyloides canis</i> , <i>Strongyloides stercoralis</i>)	10	10-12
Heartworm microfilariae (<i>Dirofilaria immitis</i>)	3-5	7-10

Note: Treatment with dithiazanine iodide for heartworm microfilariae should follow 6 weeks after therapy for adult worms.

(2) The drug is contraindicated in animals sensitive to dithiazanine iodide and should be used cautiously, if at all, in dogs with reduced renal function.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) Use for treating dogs for large roundworms, hookworms, whipworms, and strongyloides as provided for in this section has been NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111

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[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams of piperazine base (as piperazine citrate).

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use—(1) Amount.* 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; ¾ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10¼ ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum*; small strongyles; large strongyles, *Strongylus vulgaris*; and pinworms, *Oxyuris equi*.

(3) *Limitations.* Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]